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Supreme Court, U.S.
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In The

Supreme Court of the United States

MICHAEL J. McGUAN AND LILLIAN JOHNSON,

Petitioners,

v.

ENDOVASCULAR TECHNOLOGIES, INC., GUIDANT CORPORATION, ADVANCED CARDIOVASCULAR SYSTEMS, INC. AND ORIGIN MEDSYSTEMS, INC.,

Respondents.

On Petition For Writ Of Certiorari To The California Court Of Appeal Sixth Appellate District

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the FDA's approval of the Ancure medical device provides EVT and Guidant with a complete defense to McGuan and Johnson's tort claims.

2. Whether a state tort claim for fraud on patients and physicians, based on violations of Food and Drug regulations, is federally preempted under *Buckman*.

3. Whether fraud on the FDA, admitted by EVT and Guidant, is admissible evidence in McGuan and Johnson's tort claims.

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PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The opinion of the Court of Appeal of California, Sixth Appellate District, *McGuan and Johnson v. Endovascular Technologies, Inc., et al.* (App., *infra*, 1-25) is reported at 106 Cal. Rptr. 3d 277 (6th Dist. 2010). The judgments of the Santa Clara trial court in *McGuan* (App., *infra*, 26-27) and in *Johnson* (App., *infra*, 35-36) include as attachments the trial court opinions in its orders granting summary judgment (App., *infra*, 28-34 and 37-43, respectively), and in its orders denying motions to amend complaint (App., *infra*, 44-45 and 46-47, respectively), which are unreported.

JURISDICTION

The court of appeal judgment was entered on February 9, 2010. Timely petitions for hearing were denied on June 9, 2010 by the California Supreme Court (App., *infra*, 48 and 49, respectively). The jurisdiction of this Court is invoked under 28 U.S.C. § 1257.

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the Constitution provides in relevant part: "[T]he Laws of the United

States * * * shall be the supreme Law of the Land * * * any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

The relevant provisions of the Medical Device Amendment, 21 U.S.C. § 360k and § 337, are reproduced at App., *infra*, 70.

STATEMENT

This case raises important, recurring questions relating to the preemptive scope of the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360k(a) and 21 U.S.C. § 337(a), the meaning of this Court's decisions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), and the validity of efforts by litigants to circumvent Congress's intent through blanket assertions of federal preemption of genuine claims of serious bodily injuries based on violations of federal regulations.

In 1976, Congress expanded the authority of the Food and Drug Administration (FDA) to regulate medical devices, such as orthopedic bone screws and artificial arterial grafts, by enacting the MDA in order to protect the health and safety of the public. To ensure the effectiveness of the federal regulatory scheme, the MDA provides that no State may impose

any requirement relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a). The MDA also provides that "All such proceedings for the enforcement, or to restrain violations, of this Act [21 U.S.C.S. §§ 301 et seq.] shall be by and in the name of the United States." 21 U.S.C. § 337(a). These provisions have been the focus of considerable litigation over the past 20 years, and are squarely involved in these cases.

In *Lohr*, this Court interpreted and examined the foundations of preemption and the MDA's express preemption provision, and that opinion has continued to inform and influence decisions by this and most courts faced with preemption issues. In *Buckman*, this Court interpreted the MDA enforcement provisions to support an implied preemption of claims of fraud on the FDA, and that opinion has been broadly or narrowly applied. In *Riegel*, this Court concluded that the preemption provision expressly preempts all state common law claims relating to Class III medical devices, unless those claims are based on violations of FDA regulations, without mentioning the enforcement provisions or *Buckman*. In *Wyeth*, this Court reviewed the assertion of implied preemption in a pharmaceutical case, revisited the *Buckman* enforcement issues. The *Buckman* opinion, especially after the *Riegel* opinion, has engendered widespread confusion and conflicts in the lower courts, as reflected in decisions in California and in other state and federal

courts. *Wyeth* clarified implied preemption based on enforcement issues in pharmaceutical drug cases, and could also clarify implied preemption in medical device cases.

The first conflict concerns whether the MDA impliedly preempts claims that a manufacturer deceived patients and their physicians, by violating regulations, which the court below held are preempted under *Buckman* even though they are parallel claims under *Riegel* and as such are expressly not preempted by Congress in § 360k(a). In reaching it's holding the court concluded the *Buckman* "principles" concerning "fraud on the FDA" apply equally to fraud on patients and their physicians, in conflict with this court's *Wyeth* opinion, and in conflict even with the principles expressed by the California Supreme Court in a case involving other products regulated by the FDA.

Contrary to the plaintiff in *Buckman*, petitioners have not and do not attack the FDA decision to grant the initial approval or re-approval of the Ancure device as a "but for" cause of their injuries. Their proposed complaint alleges defendants' failure to comply with required regulatory obligations to investigate for serious injuries and issue Medical Device Reports (MDR) about such injuries, as well as the equipment failures which the FDA found had been fraudulently withheld. Pursuant to a strong FDA policy, all of such information in the MDRs would have been made available to the public, including to petitioners and their physicians, to be considered

separate and apart from the FDA approval of the device, and formed part of the bases for petitioners' decisions whether to use or not use the device. Such information, unlike information that is intended to only be communicated to the FDA in the application process, is intended for public consumption and thus the withholding or misstating such information to the public amounts to a fraud on patients and their physicians.

The second conflict concerns whether, after the FDA has found it was defrauded by a device manufacturer, the MDA preempts a subsequent state tort claim of injury caused by the device based on the same fraud found by the FDA as well as by additional and related fraud not found by the FDA but discovered in the state action. The court below applied *Buckman* to defeat petitioners' claim of fraud on the FDA even though in *Buckman* there was no prior investigation or finding of fraud by the FDA. If permitted, such fraud on the agency evidence would allow state judges and jurors to have the benefit of the FDA's determinations in deciding whether fraud on patients and their physicians contributed to their decisions to use the products, and thereby contributed to the cause of serious injuries.

Respondents' common law fraud on petitioners and their physicians is part of the evidence that includes the regulatory violations found by the FDA and admitted by respondents in the plea agreement briefly mentioned and discussed by the court below. App., *infra,* 7. The plea agreement resulted in

substantial fines and a civil settlement for the government, but not for injured users of the device who were not represented by the government. We know the FDA's response to the fraud it found, which makes highly likely its concurrence with petitioner's claims and appreciation for the discovery by petitioners of respondents' additional violations of regulations.

Both of these issues merit further review.

A. The Regulatory Structure of the Medical Device Amendments

In enacting the Medical Device Amendments of 1976 (MDA) (21 U.S.C. §§ 360c et seq.) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), Congress sought "to provide for the safety and effectiveness of medical devices intended for human use." *Lohr,* 518 U.S. at 474. The MDA divides medical devices into three classifications: Class I, Class II, and Class III. 21 U.S.C. § 360c(a)(1). The FDA designates as Class III those devices that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or which "present a potential unreasonable risk of illness or injury." *Id.* § 360c(a)(1)(C). A Class III device, such as the Ancure Device, receives the

most federal oversight, and requires premarket approval by the FDA.[1]

Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. 21 U.S.C. § 360e(d)(6)(A)(i). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. § 360e(d)(6); 21 CFR § 814.39(c). After premarket approval, the devices are subject to reporting requirements. 21 U.S.C. § 360i. These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, 21 CFR § 814.84(b)(2), to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, on a Medical Device Report (MDR), 21 CFR § 803.50(a), and to seek and obtain for the FDA "information that

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[1] There are two statutory exceptions to the premarket approval requirement for Class III devices not relevant here. They are the "grandfathering provision," 21 U.S.C. § 360e(b)(1)(A) and the "substantially equivalent" provision, 21 U.S.C. § 360e(b)(1)(B), often referred to as the "510(k)" process, after the section number in the original act. See *Lohr*, 518 U.S. at 478.

is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters." 21 CFR § 803.50(b)(2). The policy of the FDA is to make the MDR available to the public after redacting personal identities. 21 CFR § 803.9(a) and 21 CFR § 20.20(a)-(c).

B. Premarket Approval of the Ancure Device and Subsequent Events

The following paragraphs contain the undisputed facts and evidence found by the court below. App., *infra*, 4-8.[2]

In the spring of 1999, defendants filed a premarket approval application for the Ancure Device. On September 28, 1999, the FDA approved the Ancure Device for commercial distribution, subject to certain conditions and requirements. Within the first year after the premarket approval of the Ancure Device, several serious problems arose. They included: a limited recall of some units due to a "monofilament" problem; non-unique serial numbers; "Figure 8" problem involving wire controls; the Cassini Project involving several changes to the device;

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[2] This section contains the undisputed facts and evidence found by the court below, most all of which came from petitioners' civil discovery. App., *infra*, 4-8. Substantial additional relevant facts and evidence are contained in McGuan and Johnson's opposition to motion for summary judgment, and support for motions to amend. (Record, 941-1988) No discovery was obtained from the FDA or its employees.

off-label promotion to the medical services group; jacket retraction problem; handle breaking technique to be used to retract device if it became stuck after the graft was implanted; need for medical device report (MDR) policy; aneurysm rupture; non-validated processes; and labeling mix-ups. In October 2000, several employees informed Guidant about these problems. In response, Guidant initiated both an internal investigation and one by outside auditors. App., *infra*, 4.

As of December 14, 2000, Guidant was informed of "significant weaknesses in the quality systems" by the outside auditor. Outside counsel also gave its opinion to Guidant that the Ancure Devices "currently being manufactured" were "at least 'technically' adulterated" under federal law, presented "a potential risk to the public health," and Guidant's "continued distribution of certain devices . . . expose[d] the devices, the Company and responsible individuals to potential FDA regulatory action." *Id.*, 5.

Guidant assembled a team of employees under the supervision of Steve Wirkus to investigate the safety of the Ancure Device. The team reviewed Ancure case experience forms (E-Forms), voice mail, and complaints. Over 7,600 patients were implanted with the Ancure Device, and approximately 4,400 E-Forms were submitted. Though the E-Forms contained check boxes for equipment malfunctions and comments, they did not contain a check box for injuries except where death was an outcome. According to Wirkus, other injuries could be listed in the comment

box, but the data in the comment box was sometimes missing due to the limited size of the box.[3] No one on the team contacted anyone with knowledge of the complaints. In summarizing the data, Wirkus initially acknowledged that the "E-Form data may be under-reported," but a later report stated that the data might be "skewed." *Id.*, 5.

After Guidant became aware of an FDA investigation, outside counsel to Guidant wrote a memo indicating that Guidant would stop shipment of the Ancure Device and recall the product due to "deficiencies in the GES regulatory submission and communications with FDA." On March 16, 2001, defendants recalled the Ancure Device. On March 23, 2001, Guidant provided evasive, if not false, information to the FDA.[4] In response to the FDA's request for an audit report, Guidant also sent a report, which stated that it had "found nothing that indicated any intent or desire to hide information from FDA." The FDA subsequently reviewed several MedWatch reports and approved premarket approval supplements. On August 17, 2001, the FDA re-approved the Ancure Device. *Id.*, 6.

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[3] A new E-Form was issued in September 2001, but it [also] had no check boxes or questions about injuries. *Id.*, 5.

[4] Several specific instances of false answers to FDA questions were contained in plaintiffs' opposition to the Motions for Summary Judgment, and were uncontroverted, such as whether anyone had been contacted about whether serious injuries had occurred in the unreported incidents.

In the fall of 2001, the United States Department of Justice began an investigation and subpoenaed the independent auditor reports. Guidant's motion to quash was denied in July 2002. The trial court noted Guidant's use of these reports "for the purpose of influencing the FDA." The trial court also cited the declaration of an FDA representative, who stated that the existence of the reports persuaded the FDA "not to pursue additional regulatory measures beyond those proposed by the company." *Id.*, 6.

Though Guidant played a central role in the fraudulent conduct, EVT entered into a plea agreement in June 2003. EVT pleaded guilty to nine counts of shipping misbranded medical devices (21 U.S.C. §§ 331(a), 333(a)(2)) arising from the shipping of nine devices between November 3, 1999, and September 24, 2000, and one count of making false statements (18 U.S.C. § 1001), arising from the provision of incomplete information to an FDA inspector in July 2000. The plea agreement also states: "From September 30, 1999 to March 16, 2001, defendant introduced approximately 7,632 Devices into interstate commerce. Between September 30, 1999 and March 16, 2001, defendant filed 172 MDRs [Medical Device Reports] for the delivery system of the Ancure Device. On or about March 23, 2001, defendant disclosed to [the] FDA the existence of approximately 2,628 additional MDRs concerning the delivery system of the Ancure Device that had not been previously reported to [the] FDA, as required by law. . . . On or about March 23, 2001, defendant informed [the] FDA

that it had failed to seek prior approval to amend its instruction for use to include the Handle Breaking Technique as legally required." The plea agreement required EVT to forfeit $10.9 million as well as pay a criminal fine of $32.5 million and a civil settlement of $49 million. *Id.*, 7.

As of June 23, 2003, the Ancure Device "was no longer available." *Id.*, 8.

C. The Ancure Aortic Medical Device Litigation

In August 2004, petitioner McGuan filed a complaint in which he alleged severe injuries suffered when he was implanted with the Ancure Device on February 8, 2002. His complaint alleged eight causes of action: strict product liability (failure to warn); strict product liability (Restatement Second of Torts § 402A); negligence; breach of express warranty; breach of implied warranty; fraudulent concealment; punitive damages; and violations of the Consumer Legal Remedies Act. In June 2005, petitioner Johnson filed a first amended complaint in which she alleged severe injuries when she was implanted with the Ancure Device on May 17, 2002. Her complaint alleged the same causes of action as those alleged in McGuan's complaint. However, her complaint also added a cause of action for fraud and misrepresentation. Plaintiffs' complaints focus on defects in the design, testing, and manufacture of the Ancure Device, the failure to warn of all possible adverse side

effects, and the fraudulent concealment of the dangers and defects of the product. The complaints do not refer to violations of federal law. App., *infra*, 8.

On September 22, 2005, respondents filed a motion for summary judgment on the ground that petitioners' claims were preempted by federal law. Petitioners were granted leave to conduct, and did conduct extensive discovery. On May 5, 2008, plaintiffs filed opposition to the summary judgment motion. On May 13, 2008, petitioners McGuan and Johnson noticed motions to amend their complaints (App., *infra*, 53 and 61, respectively) attaching their proposed amended complaints and supporting their motions with the facts and evidence submitted in opposition to the motions for summary judgment. McGuan added new cause of action, No. Seven (App., *infra*, 56), and Johnson added new cause of action, No. Ten (App., *infra*, 65), alleging common law fraud on the FDA as well as on petitioners and their physicians, based on the FDA findings of fraud in June 2003 and on substantial discovered evidence of respondents intentional failures to investigate and report about serious injuries. App., *infra*, 9.

The trial court granted defendants' motions for summary judgment on the ground that petitioners' claims in their complaints were preempted by 21 U.S.C. section 360k(a) of the MDA. The trial court also ruled that plaintiffs could not avoid preemption by arguing that defendants engaged in fraud-on-the-FDA because this claim was preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S.

341. The trial court denied petitioners' motions to amend their complaints, rejecting petitioners' parallel exception argument pertaining to fraud on petitioners and their physicians. Petitioners filed timely notices of appeal following judgments of dismissal. App., *infra*, 9.

The court below affirmed the trial court's rulings. App., *infra*, 1. Petitioners McGuan and Johnson timely filed petitions for review with the California Supreme Court, which were denied. App., *infra*, 48 and 49, respectively.

D. The Court of Appeal Decision

The court below, after discussing at length the principles of federal preemption under 21 U.S.C. § 360k and *Riegel*, affirmed the dismissal of McGuan's and Johnson's original complaints, holding that the MDA preempts all of their original claims. App. *infra*, 14. As to appellants' attempted addition of a fraud cause of action, the court discussed "fraud on the FDA" claims under *Buckman* and rejected the argument that the Department of Justice investigation leading to an agreed conviction in June 2003, and removal of the Ancure device from the market a few days later, was sufficient to overcome the *Buckman* preemption of "fraud on the FDA" claims. App., *infra*, 16-19.

The court acknowledged that the new fraud cause of action also contains allegations of "fraud on patients and their physicians" based on violations of

federal requirements, and such claims are therefore entitled to be exempted from express preemption under 21 U.S.C. § 360k and this court's *Riegel* opinion. App., *infra*, 19.

However, the court then held that the *Buckman* "principles" concerning implied preemption of "fraud on the FDA" applies "with equal force to claims involving defendants' misrepresentations to plaintiffs and their physicians after March 2001"[5] and, without any further discussion, that "if plaintiffs were allowed to proceed with their state law fraud claims, a finding of liability would also 'conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives.'" App., *infra*, 19.

The court below then affirmed the denial of petitioners' motions to amend by concluding that "Here, as previously discussed, plaintiffs' proposed

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[5] No evidence exists that the FDA actually investigated violations that occurred after March 2001; thus, the lack of such findings in the Plea Agreement is not surprising. Moreover, the FDA did not find out about Defendants' fraud until July 2002 at the earliest. Furthermore, the FDA's finding or not finding of fraud is not essential to a claim of fraud on patients and their physicians and does not impliedly preempt private state claims for fraud on patients and their physicians, as discussed *infra*.

Plaintiff's fraud claims are based on violations that occurred before as well as after March 2001. (See App., *infra*, 14, fn 6 after the first sentence, for a more accurate description of petitioners' argument. The court's description of petitioners' "main issue" on appeal, in the first sentence, is not supported in the record).

amendments could not cure the complaints' defects. Accordingly, the trial court did not abuse its discretion in denying plaintiffs' motions to amend the complaints." App., *infra*, 22.

REASONS FOR GRANTING THE PETITION

The decision below creates unnecessarily one supreme court conflict between *Riegel* and *Buckman*, and extends another between *Buckman*, *Lohr* and *Wyeth*, as to vitally important and frequently recurring issues of federal law: (1) whether common law claims of "fraud on patients and physicians," based on federal regulation violations, are impliedly preempted under 21 U.S.C. § 337, *Lohr*, *Buckman* and *Wyeth*, or whether they are parallel claim exceptions under 21 U.S.C. § 360k and *Riegel*; and (2) whether this Court's decision in *Buckman* preempts common law fraud claims based, in part, on FDA findings of fraud.

Moreover, the lower court's preemption ruling is at odds with the principles discussed and laid down by the California Supreme Court in *Farm Raised Salmon Cases*, 42 Cal. 4th 1077 (2008), *cert. den. sub nom. Albertson's, Inc. v. Kanter,* 129 S. Ct. 896. The opinion in *Farm Raised Salmon Cases* directly confronted the question whether fraud claims brought in California courts were preempted by § 337 and *Buckman*, and concluded that so long as the bases for the claims were identical to federal law such claims would not be preempted.

This Court's guidance in *Lohr, Buckman, Riegel* and *Wyeth* is relevant to the preemption issues in this case. *Lohr* laid down two foundational principles for determining preemption issues, both confirmed by *Wyeth*:

> First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr, 518 U.S. 470, 485* * * * Second, "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Lohr*, * * * "We rely on the presumption because respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly preempt state-law causes of action.' *Lohr, 518 U.S. at 485* * * * ."

Buckman, which involved a single "but for" fraud on the FDA cause of action in a 501K device suit, added to the *Lohr* principles by denying application of the presumption against preemption when States have traditionally not occupied a field:

> Policing fraud against federal agencies is hardly "a field which the States have traditionally occupied," *Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230, 91 L. Ed. 1447, 67*

> *S. Ct. 1146 (1947)*, such as to warrant a presumption against finding federal preemption of a state-law cause of action. To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law.

Buckman, 531 U.S. at 347.

Then, after discussing the justifications for preempting the "fraud on the agency" claim, the *Buckman* opinion observed that the FDCA enforcement provisions (21 U.S.C.A. 331 thru 334 and 372) allow "the FDA (fn 4) * * * to make a measured response to suspected fraud upon the Agency."

> Fn 4 The FDCA leaves no doubt that it is *the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions*: "All such proceedings for the enforcement, or to restrain violations, of this chapter [sic] shall be by and in the name of the United States." *21 U.S.C. § 337(a)*."

531 U.S. at 349, emphasis added.

While the text clearly limits the ruling to "fraud on the FDA" claims, footnote 4 in *Buckman* may have introduced an ambiguity and unintended consequences. The footnote could be interpreted to preempt common law "fraud on patients and physician" as well as all other common law claims based on a manufacturer's "noncompliance with the medical device provisions."

The unfortunate effect of this consequence may be the preemption of cases otherwise qualified as an exception from express preemption under 21 U.S.C. 360k and *Riegel*, and the denial of just compensation for serious injuries caused by a manufacturer's wrongful conduct.

This Court in *Riegel* formally established the preemption of traditional common law claims brought against manufacturers of Class III medical devices, per congressional intent under § 360k, but noted that the MDA preemption provision did not preempt all possible claims.

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. *§ 360k(a)(1)*. Thus, *§ 360k* does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements. *Lohr, 518 U.S., at 495*.

Riegel, 552 U.S. at 330.

Review of this case would also allow the Court to resolve widespread uncertainty over the meaning of implied preemption under *Buckman*. In the wake of *Buckman*, uncertainty exists in lower courts over whether the MDA preempts only "fraud on the agency" claims that clearly state a "but for" causal link to the federal laws, over whether it preempts all claims of fraud that "sound" like fraud on the agency, and

even over whether, following *Riegel*, it preempts all Class III medical device claims whether or not they are based on violations of federal regulations.

Finally, there is uncertainty over whether the principles laid down in *Lohr* and affirmed in *Wyeth* have any bearing on the confusion caused by *Buckman*, e.g., whether the presumption against preemption should apply to claims not involving fraud on the FDA that are also "parallel" to federal requirements.

Because these uncertainties are attributable to ambiguities in the *Buckman* decision, or the combination of the *Buckman, Riegel, Lohr* and *Wyeth* decisions, only this Court can bring clarity to this important area of federal law.

I. This Case Is Within the Ambit of *Lohr*, *Buckman*, *Riegel* and *Wyeth*

Although the below court acknowledged that petitioners' proposed new cause of action for fraud on petitioners and their physicians stated parallel claims, based on violations of federal regulations, it nevertheless concluded that that they were preempted under *Buckman*.

> Here, though plaintiffs' fraud claims are premised on violations of FDA regulations, that does not resolve the issue. In contrast to *Riegel, Buckman* was not interpreting the MDA preemption provision. Instead, *Buckman* relied on implied preemption principles. (*Buckman, supra, 531 U.S. at pp. 348-353.*)

> Those same principles apply with equal force to claims involving defendants' misrepresentations to plaintiffs and their physicians. . . .

App., *infra*, 19.

Thus, this case touches all four of this Court's major opinions concerning medical device preemption issues. The below court has conflated implied preemption of "fraud on the FDA" claims to include "fraud on patients and their physicians" claims, based on the misapplication or misreading of this court's *Buckman* rational, or perhaps based on the unintended ambiguity in footnote 4 of the *Buckman* opinion. Because the court below merely referenced five pages of discussion in *Buckman*, it is impossible to understand its reasoning.

II. The Leading California Case On Implied Preemption Under *Buckman* Reached the Opposite Conclusion

The California Supreme Court in *Farm Raised Salmon Cases*, 42 Cal. 4th 1077, faced yet another express preemption provision in the FDCA, 21 U.S.C. § 343-1. The plaintiff filed an action alleging that various grocery stores violated state law by selling artificially colored farmed salmon without disclosing to their customers the use of color additives. The court of appeal affirmed the trial court's dismissal of the action after granting defendant's demurrer, based on implied preemption under § 337(a) of the FDCA.

The court reviewed relevant federal and state laws, including the express preemption provision pertaining to the Nutritional Labeling and Education Act of 1990 (NLEA), § 343-1, and observed that in contrast § 337 "is a standing provision, providing that 'all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.'" *Id.* at 1087. The Court further observed that § 337 and *Buckman* are concerned with the enforcement of the FDCA, not with private claims in state court:

> § 377 precludes private enforcement of the FDCA (§ 337(a); (*Buckman*) and limits the circumstances under which states may seek to enforce the FDCA in federal court (§ 337(b)). Whether or not § 337 also precludes private claims predicated on state law is the crux of the present litigation and will be discussed at greater length below. (*Id.*)

Defendants in *Farm Raised Salmon Cases* argued that the plaintiffs' claims were impliedly preempted by § 337(a) because "they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." 42 Cal. 4th at 1089; essentially, the same argument was made by the below court. App., *infra*, 17.

The California Supreme Court rejected the argument, relying heavily on this court's opinions in *Lohr* and *Bates v. Dow Agrosciences LLC*, 544 U.S. 431

(2005). First, it cited the existence of a strong presumption established in *Lohr* and *Bates* against "the existence as well as the scope of preemption" concerning § 360k, the medical devices preemption provision. 42 Cal. 4th at 1088 ("we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.") Second, it recognized the right of private suits to enforce state laws even though identical to federal FDCA laws, also based on the holdings in *Lohr* and *Bates*. *Id.* at 1093-94.

After a thorough analysis of § 343-1, continuing to draw a parallel to § 360k, *Farm Raised Salmon Cases* held that the defendants failed to meet their burden of overcoming the "strong presumption against preemption" and accordingly that "section 337 does not impliedly preempt private actions based on violations of state laws explicitly authorized by section 343-1." *Id.* at pp. 1094-1099.

Petitioners' common law claims in their proposed amended complaints are based on violations of federal regulations and parallel without imposing conflicting standards. The FDA's safety assessment of medical devices post approval is based in large part on the manufacture's reporting of implant incidents after investigation of such incidents to determine if serious injuries occurred. The prosecution of petitioners' private claims based on failures to comply with post-approval requirements therefore helps, and does

not hinder, the FDA. In sum, there is no conflict between § 337(a) and petitioners' state law claims, and their motions to amend should have been granted and their claims should not have been preempted.

The below court's *McGuan and Johnson* opinion is in conflict with *Farm Raised Salmon Cases*, as well as with *Lohr* and *Bates*, and is not justified under *Buckman*. It is now arguably in conflict also with *Wyeth,* which reaffirmed the presumption against preemption in drug cases. The presumption should also apply in device cases alleging common law "fraud on patients and physicians" claims since states historically occupied the field.

III. The Decision Below Is Incorrect

The decision is incorrect, at least in one major part. The court's justification for its holding is based on the "trumping" of the *Riegel* exception with a misapplication of the *Buckman* rationale pertaining to "fraud on the FDA."

> Here, though plaintiffs' fraud claims are premised on violations of FDA regulations, that does not resolve the issue. In contrast to *Riegel*, *Buckman* was not interpreting the MDA preemption provision. Instead, *Buckman* relied on implied preemption principles. (*Buckman*, *supra*, 531 U.S. at pp. 348-353.) *Those same principles apply with equal force to claims involving defendants'*

> *misrepresentations to plaintiffs and their physicians after March 2001.*

App., *infra*, 19; emphasis added.

There is no discussion or support for the emphasized conclusion, in *Buckman* or any other authority.

Contrary to the conclusion, petitioners' proposed new cause of action does not limit the time period of respondents' misrepresentations – respondents failed to investigate and report required information before and after March 2001; the FDA found some failures had occurred before March 2001, petitioners found other failures occurred both before and after March 2001. Second, there is no basis in *Buckman* for applying the principles concerning fraud on the FDA to fraud on petitioners and their physicians; there is no discussion of fraud on patients and their physicians in *Buckman*, and the plaintiff in *Buckman* made no such claim.

Preempting petitioners' entire claims grants complete immunity for false representations made to them or their physicians. Put another way, preemption here would eliminate claims that plaintiffs would have had under state law if the MDA had not been enacted. Finally, the "structure and purpose of the statute as a whole" does not support preempting claims of fraud on patients and their physicians. The MDA and its accompanying regulations contemplate giving federal marketing clearance of medical devices the highest priority; but its scheme also contemplates giving some independent guidance to physicians and

patients in the form of post-approval medical device reports provided by manufacturers.

Congress' included enforcement powers in the FDCA, just as state and local laws are enforceable by duly appointed agencies. The FDCA provisions do not express a congressional intent that patients cannot seek compensation for wrongs committed, whether prosecuted or not prosecuted by the FDA. Citizens can sue for injuries caused by those who violate state traffic and health laws. Congress' intent, expressed in § 360k and interpreted by *Riegel*, is that patients who are injured by the device may sue for injuries so long as their claim is based on violations of federal regulations pertaining to the device.

In accord with petitioners' position is *Woods v. Gliatech, Inc.*, 218 F. Supp. 2d 802 (W.D. Virginia 2002). In *Woods*, Gliatech, the manufacturer of an ADCONN-L medical device, failed to submit required MDRs concerning problems with the device. The MDRs "are publicly available documents. Thus, back surgeons and other medical professionals, potential back surgery patients, and the general public would have had access to the MDRs had Gliatech filed them." 218 F. Supp. 2d at 804. Subsequent to the plaintiff's back surgery, an investigation by the FDA and Department of Justice uncovered Gliatech's failure. Gliatech voluntarily recalled the device and plaintiff filed suit. A criminal information was then filed against Gliatech and a plea agreement was executed admitting violations. *Id.* The court disposed of Gliatech's preemption argument by distinguishing

the case from *Buckman* by pointing out that "In this case, Woods' fraud claim is based on material misrepresentations to "consumers and users and patients" and not on misrepresentations to the FDA. (Pl. Comp.) It, therefore, avoids the concerns identified in Buckman." *Id.* at 810. "[P]laintiff can establish his claim 'without second-guessing the FDA's decision making' and without endangering important MDA policies." *Id.*

> The court rejects the notion that Congress intended *§ 360k(a)* to preempt traditional common law causes of action in cases where a manufacturer obtained only conditional approval from the FDA to market a medical device, the FDA determined that the manufacturer committed misconduct in the approval process, and the manufacturer pled guilty to fraud on the FDA.

Id.

In the words of Justice Stevens in *Lohr*,

> [Defendant's] construction of *§ 360k* would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order "to provide for the safety and effectiveness of medical devices intended for human use." It is, to say the least, "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct," and it would take language much plainer

> than the text of *§ 360k* to convince us that Congress intended that result.

518 U.S. at 810.

The court also erred in denying petitioners' claims for "fraud on the FDA." The court below ruled that because the FDA did not formally take action to remove the Ancure device from the market, petitioners' fraud on the FDA claims were preempted by *Buckman*. App., *infra*, 18. The only known opinion since *Buckman* faced with allegations of fraud on the FDA, based on findings of fraud by the FDA, refused to preempt such claims. See *Wawrzynek v. Statprobe, Inc.*, No. 05-1342, 2007 U.S. Dist. LEXIS 80155 (E.Dist. Penn. 2007) ("Because the FDA found that fraud and wrongdoing occurred during the ADCON-L approval process, the door to the *Buckman* concurrence was opened * * * .").

IV. The Issues Presented Are Recurring and of Great Importance

While fraudulent conduct may not occur as often as unintended negligent conduct, it is perhaps more important in skewing the balance between risk and safety envisioned for the FDA's regulation of medical devices. While the FDA has the legal structure necessary to police fraud in the face of budgetary and economic cycles, as well as regulatory cycles resulting from shifts in political power, it does not always have the budget or political weal to do so. Civil suits claiming fraud on patients and surgeons, based only on

violations of federal standards, can only help the FDA achieve the goals it establishes.

On the other hand, compensation for serious injuries has been deprived for many citizens because of the federal preemption of state common law claims. Those seriously injured at the hands of others suffer the consequences. The development of federal preemption in recent years has deprived those seriously injured of the traditional means of seeking compensation from those responsible, without any alternative. The *McGuan and Johnson* opinion presently stands as a barrier to California courts. This court is the "last resort" for such relief.

The primary issue to decide in this case, because of the below court's conclusion that no amendment to petitioners' complaint would prevent preemption, is the same issue addressed and answered by Justice Stevens in *Wyeth*: "The question we must decide is whether the FDA's approvals provide Wyeth with a complete defense to Levine's tort claims." *Wyeth*, 129 S. Ct. at 1191. His conclusion should apply as well to petitioners' petition.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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MICHAEL J. McGUAN, Plaintiff and Appellant, v. ENDOVASCULAR TECHNOLOGIES, INC., et al., Defendants and Respondents. LILLIAN JOHNSON, Plaintiff and Appellant, v. ENDOVASCULAR TECHNOLOGIES, INC., Defendant and Respondent.

H033287, H033290

COURT OF APPEAL OF CALIFORNIA, SIXTH APPELLATE DISTRICT

182 Cal. App. 4th 974; 106 Cal. Rptr. 3d 277; 2010 Cal. App. LEXIS 310

February 9, 2010, Filed

COUNSEL: Joseph E. Russell for Plaintiffs and Appellants.

Jack B. McCowan, Jr., Michael O'Donnell and Sean G. Saxon for Defendants and Respondents.

JUDGES: Opinion by Mihara, J., with Elia, Acting P. J., and McAdams, J., concurring.

OPINION BY: Mihara

OPINION

MIHARA, J. – The Food and Drug Administration (FDA) approved the Ancure Endograft System (Ancure Device) for use by surgeons to treat abdominal aortic aneurysms. Plaintiffs Michael J. McGuan and Lillian Johnson, who suffered severe injuries after they were implanted with this device, brought products liability and personal injury actions

against defendants Endovascular Technologies, Inc. (EVT), Guidant Corporation (Guidant), Advanced Cardiovascular Systems, Inc., and Origin Medsystems, Inc.[1] The trial court granted defendants' motions for summary judgment on the ground that plaintiffs' claims were preempted by federal law. The trial court also denied plaintiffs' motions to amend their complaints, and granted defendants' motions to seal portions of the record. Plaintiffs have filed timely appeals from the judgments of dismissal.[2]

I. Federal Regulation of Medical Devices

In enacting the Medical Device Amendments of 1976 (MDA) (21 U.S.C. § 360c et seq.) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), Congress sought to "'to provide for the safety and effectiveness of medical devices intended for human use.'" (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 474 [135 L.Ed.2d 700, 116 S.Ct. 2240] (*Medtronic*).) The MDA divides medical devices into three classifications: class I, class II, and class III. (21

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[1] EVT designed, manufactured, and distributed the Ancure Device. Guidant is the parent corporation of EVT. Advanced Cardiovascular Systems, Inc., had some involvement in the design and testing of the Ancure Device. Some employees of Origin Medsystems may have been involved in the design or testing of the Ancure Device.

[2] This court has denied the parties' stipulated request to consolidate the appeals. However, on its own motion, this court will consider the cases together for purposes of briefing, oral argument, and decision.

U.S.C. § 360c(a)(1).) A class III device, such as the Ancure Device, receives the most federal oversight, and requires premarket approval by the FDA.[3] (*Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312, 315-318 [169 L.Ed.2d 892, 128 S.Ct. 999, 1003-1004] (*Riegel*).) This "rigorous" process requires an applicant to submit "full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a 'full statement' of the device's 'components, ingredients, and properties and of the principle or principles of operation'; 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device'; samples or device components required by the FDA; and a specimen of the proposed labeling. (§ 360e(c)(1).)" (*Riegel*, at p. 318 [128 S.Ct. at p. 1004].)

The FDA spends an "average of 1,200 hours" on each premarket approval application. (*Medtronic*, *supra*, 518 U.S. at p. 477.) In determining whether to grant premarket approval of a class III device, the FDA must, among other things, "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use."

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[3] There are two statutory exceptions to the premarket approval requirement for class III devices not relevant here. They are the "grandfathering provision" (*see* 21 U.S.C. § 360e(b)(1)(A)), and the "substantially equivalent" provision (21 U.S.C. § 360e(b)(1)(B)).

(21 U.S.C. § 360c(a)(2)(C).) The FDA will also "rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance" of the device's "safety and effectiveness." (21 U.S.C. § 360e(d)(1)(A).) In the event that the FDA grants premarket approval, it may condition its approval on adherence to various requirements. (21 U.S.C. §§ 360e(d), 360j(e)(1).) After approval, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." (*Riegel*, *supra*, 552 U.S. at p. 319 [128 S.Ct. at p. 1005].)

II. Statement of Facts[4]

In the spring of 1999, defendants filed a premarket approval application for the Ancure Device. On September 28, 1999, the FDA approved the Ancure Device for commercial distribution, subject to certain conditions and requirements.

Within the first year after the premarket approval of the Ancure Device, several serious problems arose. They included: a limited recall of some units due to a "monofilament" problem; nonunique serial numbers; "Figure 8" problem involving wire controls;

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[4] The statement of facts is based on undisputed facts and evidence presented by plaintiffs in opposition to the motion for summary judgment.

the Cassini Project involving several changes to the device; off-label promotion to the medical services group; jacket retraction problem; handle breaking technique to be used to retract device if it became stuck after the graft was implanted; need for medical device report (MDR) policy; aneurysm rupture; nonvalidated processes; and labeling mixups. In October 2000, several employees informed Guidant about these problems. In response, Guidant initiated both an internal investigation and one by outside auditors.

As of December 14, 2000, Guidant was informed of "significant weaknesses in the quality systems" by the outside auditor. Outside counsel also gave its opinion to Guidant that the Ancure Devices "currently being manufactured" were "at least 'technically' adulterated" under federal law, presented "a potential risk to the public health," and Guidant's "continued distribution of certain devices . . . expose[d] the devices, the Company and responsible individuals to potential FDA regulatory action."

Guidant assembled a team of employees under the supervision of Steve Wirkus to investigate the safety of the Ancure Device. The team reviewed Ancure case experience forms (E-Forms), voice mail, and complaints. Over 7,600 patients were implanted with the Ancure Device, and approximately 4,400 E-Forms were submitted. Though the E-Forms contained check boxes for equipment malfunctions and comments, they did not contain a check box for injuries except where death was an outcome. According to

Wirkus, other injuries could be listed in the comment box, but the data in the comment box was sometimes missing due to the limited size of the box.[5] No one on the team contacted anyone with knowledge of the complaints. In summarizing the data, Wirkus initially acknowledged that the "E-Form data may be under-reported," but a later report stated that the data might be "skewed."

After Guidant became aware of an FDA investigation, outside counsel to Guidant wrote a memo indicating that Guidant would stop shipment of the Ancure Device and recall the product due to "deficiencies in the GES regulatory submission and communications with FDA." On March 16, 2001, defendants recalled the Ancure Device.

On March 23, 2001, Guidant provided evasive, if not false, information to the FDA. In response to the FDA's request for an audit report, Guidant also sent a report, which stated that it had "found nothing that indicated any intent or desire to hide information from FDA."

The FDA subsequently reviewed several MedWatch reports and approved premarket approval supplements. On August 17, 2001, the FDA reapproved the Ancure Device.

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[5] A new E-Form was issued in September 2001, but it had no check boxes or questions about injuries.

In the fall of 2001, the United States Department of Justice began an investigation and subpoenaed the independent auditor reports. Guidant's motion to quash was denied in July 2002. The trial court noted Guidant's use of these reports "for the purpose of influencing the FDA." The trial court also cited the declaration of an FDA representative, who stated that the existence of the reports persuaded the FDA "not to pursue additional regulatory measures beyond those proposed by the company."

In April 2002, the FDA approved an aortoiliac version of the Ancure Device, and approved and required additional language pertinent to its use.

Though Guidant played a central role in the fraudulent conduct, EVT entered into a plea agreement in June 2003. EVT pleaded guilty to nine counts of shipping misbranded medical devices (21 U.S.C. §§ 331(a), 333(a)(2)) arising from the shipping of nine devices between November 3, 1999, and September 24, 2000, and one count of making false statements (18 U.S.C. § 1001), arising from the provision of incomplete information to an FDA inspector in July 2000. The plea agreement also states: "From September 30, 1999 to March 16, 2001, defendant introduced approximately 7,632 Devices into interstate commerce. [¶] Between September 30, 1999 and March 16, 2001, defendant filed 172 MDRs [Medical Device Reports] for the delivery system of the Ancure Device. [¶] On or about March 23, 2001, defendant disclosed to [the] FDA the existence of approximately 2,628 additional MDRs concerning the delivery

system of the Ancure Device that had not been previously reported to [the] FDA, as required by law. . . . [¶] On or about March 23, 2001, defendant informed [the] FDA that it had failed to seek prior approval to amend its instruction for use to include the Handle Breaking Technique as legally required." The plea agreement required EVT to forfeit $ 10.9 million as well as pay a criminal fine of $ 32.5 million and a civil settlement of $ 49 million.

As of June 23, 2003, the Ancure Device "was no longer available."

III. Statement of the Case

In August 2004, McGuan filed a complaint in which he alleged that he suffered severe injuries after he was implanted with the Ancure Device on February 8, 2002. His complaint alleged eight causes of action: strict products liability (failure to warn); strict products liability (Rest.2d of Torts, § 402A); negligence; breach of express warranty; breach of implied warranty; fraudulent concealment; punitive damages; and violations of the Consumers Legal Remedies Act (Civ. Code, § 1750 et seq.). In June 2005, Johnson filed a first amended complaint in which she alleged that she suffered severe injuries after she was implanted with the Ancure Device on May 17, 2002. Her complaint alleged the same causes of action as those alleged in McGuan's complaint. However, her complaint also added a cause of action for fraud and misrepresentation. Plaintiffs' complaints focus on

defects in the design, testing, and manufacture of the Ancure Device, the failure to warn of all possible adverse side effects, and the fraudulent concealment of the dangers and defects of the product. The complaints do not refer to violations of federal law.

On September 22, 2005, defendants filed a motion for summary judgment on the ground that plaintiffs' claims were preempted by federal law. Plaintiffs were granted leave to conduct discovery. On May 5, 2008, plaintiffs filed opposition to the summary judgment motion. The day after defendants filed their reply, plaintiffs brought motions to amend their complaints.

The trial court granted defendants' motions for summary judgment on the ground that plaintiffs' claims were preempted by 21 United States Code section 360k(a) of the MDA. The trial court also ruled that plaintiffs could not avoid preemption by arguing that defendants engaged in fraud on the FDA because this claim was preempted under *Buckman Co. v. Plaintiffs' Legal Comm.* (2001) 531 U.S. 341 [148 L.Ed.2d 854, 121 S.Ct. 1012] (*Buckman*). The trial court subsequently denied plaintiffs' motions to amend their complaints, and granted defendants' motions to seal audit reports. Following judgments of dismissal, plaintiffs filed timely notices of appeal.

IV. Discussion

A. Motion for Summary Judgment

1. Standard of Review

In bringing a motion for summary judgment, a party bears the "burden of persuasion" that there are no triable issues of material fact and that the moving party is entitled to judgment as a matter of law. (*Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 850 [107 Cal.Rptr.2d 841, 24 P.3d 493] (*Aguilar*).) A defendant may be entitled to judgment as a matter of law where there is "an affirmative defense to that cause of action." (Code Civ. Proc., § 437c, subd. (o)(2).) After the defendant meets the burden of establishing all elements of the affirmative defense, the burden shifts to the plaintiff to show that a genuine issue of material fact exists as to that defense. (Code Civ. Proc., § 437c, subd. (p)(2).) "There is a triable issue of material fact if, and only if, the evidence would allow a reasonable trier of fact to find the underlying fact in favor of the party opposing the motion in accordance with the applicable standard of proof." (*Aguilar*, at p. 850, fn. omitted.) Our review of a ruling on a summary judgment motion is de novo. (*County of Santa Clara v. Atlantic Richfield Co.* (2006) 137 Cal.App.4th 292, 316 [40 Cal.Rptr.3d 313].)

2. Federal Preemption

(1) Congress has the power under the supremacy clause of article VI of the federal Constitution to preempt state law. "[S]tate law that conflicts with

federal law is 'without effect.'" (*Cipollone v. Liggett Group, Inc.* (1992) 505 U.S. 504, 516 [120 L.Ed.2d 407, 112 S.Ct. 2608], quoting *Maryland v. Louisiana* (1981) 451 U.S. 725, 746 [68 L.Ed.2d 576, 101 S.Ct. 2114].) As the United States Supreme Court has explained, federal law preempts state law in three circumstances. "First, Congress can define explicitly the extent to which its enactments pre-empt state law. [Citation.] Pre-emption fundamentally is a question of congressional intent, [citation] and when Congress has made its intent known through explicit statutory language, the courts' task is an easy one. [¶] Second, in the absence of explicit statutory language, state law is pre-empted where it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively. . . . [¶] Finally, state law is pre-empted to the extent that it actually conflicts with federal law." (*English v. General Electric Co.* (1990) 496 U.S. 72, 78-79 [110 L.Ed.2d 65, 110 S.Ct. 2270].)

The preemption provision of the MDA states in relevant part: "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement – [¶] (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and [¶] (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." (21 U.S.C. § 360k(a).)

(2) The United States Supreme Court considered the scope of this preemption provision in *Riegel*, *supra*, 552 U.S. 312 [128 S.Ct. 999]. In *Riegel*, the plaintiffs alleged that the defendant's catheter, a class III device, was "designed, labeled, and manufactured in a manner that violated" state common law, and that these defects caused severe injuries. (*Riegel*, at p. 320 [128 S.Ct. at p. 1005].) The plaintiffs' complaint stated claims for "strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter." (*Riegel*, at p. 320 [128 S.Ct. at p. 1006].) At issue was whether the preemption provision in the MDA barred common law claims that challenged the safety and effectiveness of class III devices which had received premarket approval by the FDA. (*Riegel*, at p. 315 [128 S.Ct. at p. 1002].) In resolving this issue, the court articulated a two-part test: (1) "whether the Federal Government has established requirements applicable to" the defendant's catheter, and (2) if so, whether the "common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." (*Riegel*, at pp. 321-322 [128 S.Ct. at p. 1006].)

The court first found that premarket approval imposes federal requirements because it is granted "only after [the FDA] determines that a device offers a reasonable assurance of safety and effectiveness" and because "the FDA requires a device that has

received premarket approval to be made with almost no deviations from the specifications in its approval application." (*Riegel*, *supra*, 552 U.S. at p. 323 [128 S.Ct. at p. 1007].) Turning to the second question, the court, relying on *Medtronic*, *supra*, 518 U.S. at page 512, concluded that tort duties under common law impose "'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." (*Riegel*, at pp. 323-324 [128 S.Ct. at p. 1007].) As the court explained, "excluding common-law duties from the scope of pre-emption would make little sense. State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court." (*Riegel*, at p. 325 [128 S.Ct. at p. 1008].) Accordingly, the court held that the plaintiffs' common law claims were preempted by federal law. (*Riegel*, at pp. 323-324 [128 S.Ct. at pp. 1007-1008].)

(3) Here, though plaintiffs' complaints are based, in part, on alleged defects in the design, testing, and manufacture of the Ancure Device as well as the failure to warn of all possible adverse side effects, they do not allege that defendants violated FDA regulations. Since the FDA reapproved the Ancure Device prior to plaintiffs' surgeries, the FDA gave its approval of the device's design, testing, intended use, manufacturing methods, performance standards, and labeling. Thus, to the extent that plaintiffs' complaints allege that the Ancure Device was unsafe and its warnings were inadequate, they are seeking to impose requirements that are "'different from, or in addition to'" the MDA. Consequently, the state law claims for strict products liability, negligence, breach of express warranty, breach of implied warranty, and violations of the Consumers Legal Remedies Act are preempted under the MDA.

Plaintiffs, however, focus on defendants' alleged fraudulent conduct after March 2001. They argue that their "causes of action are not preempted, by virtue of fraud on the FDA" or, alternatively, their "cause of action for fraud and misrepresentation is not preempted."[6] Defendants counter that plaintiffs

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[6] Plaintiffs identify the "main issue" on appeal as whether preemption should apply when "re-approval for the device was obtained by [defendants'] fraud on the FDA, proven by the FDA with severe consequents on defendant[s]." Plaintiffs argue that their "claims all stem from the fraudulent conduct of Defendants during 2001 in the context of the recall and reapproval of Ancure." They further contend that defendants "violated several

(Continued on following page)

have failed to plead fraud-on-the-FDA claims and that any such claims are "not legally cognizable."

We first note that McGuan's complaint does not allege a cause of action for fraud on the FDA or fraud and misrepresentation. It states a cause of action for "fraudulent concealment," which alleges that defendants "had the duty and obligation to disclose to Plaintiff and to Plaintiff's physicians, the true facts concerning the Ancure Device product; that is, that said product was dangerous, defective, and likely to cause serious consequences to users, including injuries as herein occurred." This cause of action does not refer to the FDA's reapproval of the Ancure Device. Nor does it allege that defendants violated any federal regulations or provided inaccurate information to the FDA in the premarket approval supplements submitted prior to the reapproval. In order for McGuan to prevail on the cause of action for fraudulent concealment, the jury would be required to find that the warnings, which were approved by the FDA, were inadequate. Thus, this cause of action would impose "requirements" that are "'different from, or in addition to'" those imposed by the FDA,

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key FDA regulations, such as the PMA conditions and regulations requiring thorough investigations and reporting of injuries" and these "violations of FDA reporting and other regulations and criminally fraudulent conduct led to the FDA's reapproval of Ancure and marketing of Ancure while still violating the investigating and reporting regulations that preceded" plaintiffs' surgeries.

and consequently would be preempted. (*Riegel*, *supra*, 552 U.S. at p. 329 [128 S.Ct. at p. 1011].)

We next consider Johnson's first amended complaint. Though this complaint does not specifically refer to a fraud-on-the-FDA claim, it alleges that, after the FDA's reapproval of the Ancure Device in August 2001, defendants "withheld from the FDA, surgeons and public, reports of serious failures and resulting problems caused by" the device. The complaint also states a cause of action for fraud and misrepresentation that alleges defendants failed to disclose to her and her physicians that the Ancure Device was "dangerous, defective, and likely to cause serious consequences to users" and that defendants "made material misrepresentations that were calculated to deceive the medical community, *governmental agencies*, and Plaintiff. . . ." (Italics added.)

For purposes of argument, we will assume that plaintiffs have, or could have, stated causes of action for fraud on the FDA. We conclude, however, that these claims are preempted under *Buckman*, *supra*, 531 U.S. 341.

In *Buckman*, the plaintiffs suffered injuries after orthopedic bone screws were implanted in their spines. (*Buckman*, *supra*, 531 U.S. at p. 343.) The plaintiffs then brought state tort law claims in which they alleged that the defendant made fraudulent representations to the FDA in obtaining approval to market these class III devices, and they would not have been injured if these representations had not

been made. (*Ibid.*) The *Buckman* court began its discussion by observing that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' [citation]" and thus the nature of the plaintiffs' claims was insufficient to warrant a presumption against preemption. (*Buckman*, at p. 347.) The court based this conclusion on the principle that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." (*Ibid.*)

Based on this "analytical framework," the court held that the state law fraud-on-the-FDA claims conflicted with, and thus, were impliedly preempted by federal law. (*Buckman*, *supra*, 531 U.S. at p. 348.) As the court explained, "[t]he conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." (*Ibid.*) After reviewing the extensive disclosure requirements of the MDA and the provisions governing the detection, deterrence and punishment of false statements made during the approval process, the court concluded that state tort law fraud-on-the-FDA claims would "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's

judgment and objectives." (*Buckman*, at pp. 349-350.) Since the court held that the claims were impliedly preempted, it did not consider whether the claims were expressly preempted under 21 United States Code section 360k. (*Buckman*, at p. 348, fn. 2.)

Plaintiffs attempt to distinguish the present case from *Buckman* on the ground that the "FDA had not investigated the Buckman defendant for any alleged wrongdoing." They point out that "the FDA took strong action against" defendants and that Justice Stevens's concurring opinion in *Buckman* is "an invitation, as it were, to bring a case involving fraud 'policed' by the FDA."

In the concurring opinion, Justice Stevens suggested that *Buckman* would be "a different case" if "the FDA had determined that petitioner had committed fraud during the § 510(k) process and had then taken the necessary steps to remove the harm-causing product from the market." (*Buckman*, *supra*, 531 U.S. at p. 354.) However, neither requirement is present in the case before us. Though defendants were prosecuted and entered into a plea agreement for fraudulent conduct that occurred before March 2001, the FDA took no action against defendants for their conduct in seeking reapproval in August 2001. Instead, the FDA continued to allow the Ancure Device to be marketed, and even approved a premarket approval supplement in April 2002. Since the FDA failed to take action against defendants for any alleged fraudulent conduct after March 2001, *Buckman* is controlling. Accordingly, plaintiffs' state

law tort claims for fraud on the FDA are preempted by federal law.

Plaintiffs next argue that *Buckman* does not apply to causes of action for fraud on patients and their physicians. In *Riegel*, the court noted that the MDA preemption provision did "not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements."[7] (*Riegel*, *supra*, 552 U.S. at p. 330 [128 S.Ct. at p. 1011].) Thus, they assert that their state fraud claims are not different from or in addition to federal requirements.

Here, though plaintiffs' fraud claims are premised on violations of FDA regulations, that does not resolve the issue. In contrast to *Riegel*, *Buckman* was not interpreting the MDA preemption provision. Instead, *Buckman* relied on implied preemption principles. (*Buckman*, *supra*, 531 U.S. at pp. 348-353.) Those same principles apply with equal force to claims involving defendants' misrepresentations to plaintiffs and their physicians after March 2001. It is undisputed that the FDA found no violations of federal regulations after March 2001. Thus, if plaintiffs were allowed to proceed with their state law

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[7] In *Riegel*, the court declined to consider whether the plaintiffs had stated parallel claims because the issue was not raised before the Second Circuit or in their petition for review. (*Riegel*, *supra*, 552 U.S. at p. 330 [128 S.Ct. at p. 1011].)

fraud claims, a finding of liability would also "conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." (*Buckman*, at p. 350.)

Plaintiffs next rely on *Altria Group, Inc. v. Good* (2008) 555 U.S. ___ [172 L.Ed.2d 398, 129 S.Ct. 538] (*Altria*), and argue that "a state law fraud claim must now be considered under Altria." In *Altria*, the plaintiffs brought state law claims against cigarette manufacturers, alleging that they fraudulently advertised that their light cigarettes had less tar and nicotine than regular brands. (*Altria*, at p. ___ [129 S.Ct. at p. 541].) After considering the scope of the express preemption provisions of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. § 1331 et seq.), the court held that the plaintiffs' state law fraud claims were not preempted by federal law. (*Altria*, at pp. ___-___ [129 S.Ct. at pp. 544-549].) *Altria* is distinguishable from the present case on two grounds. First, as the *Altria* court acknowledged, the language in the MDA's preemption provision was "much broader" than that in the statute before it. (*Altria*, at p. ___ [129 S.Ct. at p. 549].) Second, the *Altria* court rejected the defendants' argument that the plaintiffs' claim was impliedly preempted because, if allowed, it would frustrate the FTC's (Federal Trade Commission) policy of promoting the consumption of low tar cigarettes. (*Ibid.*) The court reasoned that "[e]ven if such a regulatory policy could provide a basis for obstacle pre-emption, [the defendants'] description of the FTC's actions in this regard are inaccurate." (*Ibid.*)

In contrast to *Altria*, *Buckman* acknowledged the FDA's role in detecting, deterring, and punishing fraud. Thus, *Altria* does not compel a different conclusion in the present case.

B. Motion to Amend Complaint

Plaintiffs next contend that the trial court erred in denying their motions to amend their complaints. They purport to incorporate by reference the same authorities and arguments submitted to support their motions in the trial court.

(4) California Rules of Court, rule 8.204(a)(1)(B) requires that appellate briefs "support each point by argument and, if possible, by citation of authority." "It is well settled that the Court of Appeal does not permit incorporation by reference of documents filed in the trial court. (*Colores v. Board of Trustees* (2003) 105 Cal.App.4th 1293, 1301, fn. 2 [130 Cal.Rptr.2d 347] ['[I]t is not appropriate to incorporate by reference, into a brief, points and authorities contained in trial court papers, even if such papers are made a part of the appellate record']. . . .)" (*Soukup v. Law Offices of Herbert Hafif* (2006) 39 Cal.4th 260, 294, fn. 20 [46 Cal.Rptr.3d 638, 139 P.3d 30].) A Court of Appeal may refuse to consider arguments incorporated by reference. (*Parker v. Wolters Kluwer United States, Inc.* (2007) 149 Cal.App.4th 285, 290-291 [57 Cal.Rptr.3d 18] (*Parker*).) Thus, we have not considered these arguments. Since plaintiffs have failed to

submit any other arguments or authorities, the issue has been waived.

In any event, plaintiffs' contentions have no merit. Plaintiffs sought to amend their complaints by adding causes of action for fraud on the FDA as well as fraud on plaintiffs and their physicians based on defendants' failure to comply with federal regulations by providing accurate information to the FDA. Courts are liberal in allowing the amendment of pleadings at any stage of the proceedings where the amendment does not cause prejudice to the rights of other parties. (*Hayutin v. Weintraub* (1962) 207 Cal.App.2d 497, 505 [24 Cal.Rptr. 761].) We review the trial court's determination on this issue under the abuse of discretion standard. (*Id.* at pp. 505-506.) However, a trial court does not abuse its discretion in denying leave to amend "if it appears from the complaint that under applicable substantive law there is no reasonable possibility that an amendment could cure the complaint's defect." (*Heckendorn v. City of San Marino* (1986) 42 Cal.3d 481, 486 [229 Cal.Rptr. 324, 723 P.2d 64].) Here, as previously discussed, plaintiffs' proposed amendments could not cure the complaints' defects. Accordingly, the trial court did not abuse its discretion in denying plaintiffs' motions to amend the complaints.

C. Motion to Seal Records

Plaintiffs also argue that the trial court erred in granting defendants' motion to seal documents.

Plaintiffs purport to incorporate by reference the same authorities and arguments filed in opposition to defendants' motions in the trial court. As previously discussed, we refuse to consider authorities and arguments incorporated by reference. (*Parker*, *supra*, 149 Cal.App.4th at pp. 290-291.) Even if we were to consider plaintiffs' arguments, we would reject them.

In the present case, the trial court found that the records "contain trade secrets and are protected from disclosure under federal law. The Court further finds that in weighing the public's right to access against the Defendant's right to maintain the confidentiality of its trade secrets, the right to privacy clearly outweighs the public's right. This overriding interest supports sealing the records in question. The Court further finds that the [proposed] sealing of records is narrowly tailored and no less restrictive means exists to achieve the overriding interest."

The trial court "may order that a record be filed under seal only if it expressly finds facts that establish: [¶] (1) There exists an overriding interest that overcomes the right of public access to the record; [¶] (2) The overriding interest supports sealing the record; [¶] (3) A substantial probability exists that the overriding interest will be prejudiced if the record is not sealed; [¶] (4) The proposed sealing is narrowly tailored; and [¶] (5) No less restrictive means exist to achieve the overriding interest." (Cal. Rules of Court, rule 2.550(d).) Courts have found that the protection of trade secrets is an interest that can support sealing records in a civil proceeding. (*In re Providian Credit*

Card Cases (2002) 96 Cal.App.4th 292, 298-299 & fn. 3 [116 Cal.Rptr.2d 833] (*Providian*).) "'Trade secret' means information, including a formula, pattern, compilation, program, device, method, technique, or process, that: [¶] (1) Derives independent economic value, actual or potential from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and [¶] (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." (Civ. Code, § 3426.1, subd. (d).) We review the trial court's decision to order the documents sealed under the abuse of discretion standard, and any factual determinations made in connection with that decision will be upheld if they are supported by substantial evidence. (*Providian*, at p. 299.)

Here, the trial court made the requisite findings and these findings are supported by substantial evidence. Defendants submitted the declaration of Kristen Honl, Guidant's director of global compliance, in support of their motion. Honl stated that the records discuss the details of defendants' "quality system procedures, complaint handling procedures, device tracking procedures, process validation procedures, and corrective action procedures." According to Honl, these records "would have economic value to many medical device manufacturers, including Defendants' competitors, because they reveal the business methods and processes Defendants have developed to comply with the requirement of very technical FDA regulations." She further noted that

the "value and utility of this information is not completely dependent on the specific design of the device being manufactured, but could have application across a range of different Class III medical devices . . . [and that these records] are maintained as confidential and disseminated within Defendants' organization on a limited basis." Thus, the trial court did not abuse its discretion in granting defendants' motion to seal records.

V. Disposition

The judgments are affirmed.

Elia, Acting P. J., and McAdams, J., concurred.

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SUPERIOR COURT OF CALIFORNIA

COUNTY OF SANTA CLARA –
UNLIMITED CIVIL JURISDICTION

MICHAEL J. MCGUAN, Plaintiff, v. ENDOVASCULAR TECHNOLOGIES, INC., GUIDANT CORPORATION, ADVANCED CARDIOVASCULAR SYSTEMS, INC., and ORIGIN MEDSYSTEMS, INC., Defendants.	Case No.: 1-04-CV-025603 **JUDGMENT**

On May 19, 2008, this Court issued an order, a copy of which is attached hereto as **Exhibit A**, granting the Motion for Summary Judgment, or alternatively, for Summary Adjudication, of defendants ENDOVASCULAR TECHNOLOGIES, INC., GUIDANT CORPORATION, ADVANCED CARDIOVASCULAR SYSTEMS, INC., and ORIGIN MEDSYSTEMS, INC. (hereinafter "DEFENDANTS"), as to all claims.

IT IS THEREFORE HEREBY ORDERED, ADJUDGED AND DECREED that judgment be entered for DEFENDANTS and against plaintiff MICHAEL J. McGUAN, and that this action be dismissed with prejudice as to DEFENDANTS.

Dated: Jun 13 2008 /s/ Jack Komar
HON. JACK KOMAR
JUDGE OF THE
SUPERIOR COURT

EXHIBIT A

ORDER AFTER HEARING REGARDING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT, OR ALTERNATIVELY, FOR SUMMARY ADJUDICATION

SUPERIOR COURT OF CALIFORNIA

COUNTY OF SANTA CLARA

MICHAEL J. MCGUAN,

Plaintiff,

vs.

ENDOVASCULAR TECHNOLOGIES, INC., GUIDANT CORPORATION, ADVANCED CARDIOVASCULAR SYSTEMS, INC., and ORIGIN MEDSYSTEMS, INC.,

Defendants.

Case No.:
1-04-CV-025603

ORDER AFTER HEARING REGARDING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT, OR ALTERNATIVELY, FOR SUMMARY ADJUDICATION

Hearing Date:
May 16, 2008
Time: 9:00 a.m.
Department:
17C/Complex Civil

Judge: Hon. Jack Komar

This is a products liability and personal injury action. Plaintiff Michael McGuan ("McGuan") alleges he was injured after a defective medical device, the Ancure Endograft System ("ANCURE System"), was implanted in him, The device is used for abdominal aortic aneurysm repair. Defendants are alleged to have designed, manufactured, advertised, and sold the product.

McGuan's Complaint, filed on August 23, 2004, sets forth the following causes of action: [1] Strict

Product Liability (Failure to Warn); [2] Strict Product Liability (Pursuant to Restatement Second of Torts §402A (1965)); [3] Negligence; [4] Breach of Express Warranty; [5] Breach of Implied Warranty; [6] Fraudulent Concealment; [7] Punitive Damages; and [8] Violations of the Consumer Legal Remedies Act, Civil Code § 1750, *et seq.*

Defendants now move for summary judgment or, in the alternative, summary adjudication based on federal preemption.

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Defendants contend that the United States Food and Drug Administration's ("FDA") premarketing approval ("PMA") process imposes "requirements" that preempt additional or different state requirements. The PMA process is used for Class III devices, which receive the most federal oversight. The ANCURE System is a Class III device.

Under the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act ("MDA") [21 USCS §§ 301 *et seq.*],

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act
>
> (21 USCS §360k.)

The PMA process imposes "requirements" under the MDA and state claims underlying negligence, strict-liability, and implied-warranty causes of action also constitute "requirements" and are therefore preempted under the MDA. (*Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008).)

Plaintiff McGuan alleges in his complaint under state law that defendants failed to perform adequate testing and failed to provide adequate warning to users of the ANCURE System. However, the uncontradicted evidence is that the FDA approved the testing, and specified the warning requirements used by defendants. To the extent McGuan contends defendants needed to perform further testing and provide additional warnings, those would be additional requirements that are preempted by the MDA because of the FDA's earlier approval through the PMA process.

McGuan argues that where the FDA has acted upon the fraudulent conduct of the defendant, a plaintiff's state law claims will not be preempted, citing the concurring opinion of Justice Stevens in

Buckman Co. v. Plaintiffs' Legal Committee (2001) 531 U.S. 341. *Buckman* involved injuries resulting from the use of orthopedic bone screws. (*Buckman Co. v. Plaintiffs' Legal Committee, supra,* 531 U.S. at p. 343.) The majority opinion in Buckman held that:

> [T]he plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law.
>
> (*Id.* at p. 348.)

Justice Stevens's concurrence in *Buckman* opined that " . . . [t]his would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the § 510(k) process and had then taken the necessary steps to remove the harm-causing product from the market. Under those circumstances, respondent's state-law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions. In such a case, a plaintiff would be able to establish causation without second-guessing the FDA's decision-making or overburdening its personnel, thereby

alleviating the Government's central concerns regarding fraud-on-the-agency claims." (*Buckman Co. v. Plaintiffs' Legal Committee, supra,* 531 U.S. at p. 354.)

While McGuan argues that he should be permitted to proceed on claims that are premised on fraud on the FDA, citing the Stevens concurrence in *Buckman* (*supra*), McGuan neither pleads such in his complaint relating to the approval nor presents any evidence that would establish there was any fraud on the FDA that affected the pre-approval process that preceded the surgery and implantation of the device; nor does he plead or present evidence that the FDA withdrew its approval and ordered the device off the market. To the contrary, Defendants present evidence that the FDA never removed the ANCURE System from the market, but rather on August 17, 2001, it re-approved the system. McGuan provides no evidence showing otherwise. Thus, even if Justice Stevens's concurring opinion is good law, there is no basis for its application here.

This is essentially a defective device and failure to warn case. Therefore, McGuan's Complaint is preempted by the MDA because the ANCURE System was approved and then reapproved by the FDA after going through the PMA process.

ORDER

Defendants' motion for summary judgment is GRANTED.

SO ORDERED,

Dated: May 19, 2008 /s/ Jack Komar
Judge of the Supreme Court
JACK KOMAR

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SUPERIOR COURT OF CALIFORNIA

COUNTY OF SANTA CLARA – UNLIMITED CIVIL JURISDICTION

LILLIAN JOHNSON, Plaintiff, v ENDOVASCULAR TECHNOLOGIES, INC., Defendant.	Case No.: 1-05-CV-037784 **JUDGMENT**

On May 19, 2008, this Court issued an order, a copy of which is attached hereto as **Exhibit A**, granting the Motion for Summary Judgment, or

alternatively, for Summary Adjudication, of defendant ENDOVASCULAR TECHNOLOGIES, INC., as to all claims.

IT IS THEREFORE HEREBY ORDERED, ADJUDGED AND DECREED that judgment be entered for defendant ENDOVASCULAR TECHNOLOGIES, INC. and against plaintiff LILLIAN JOHNSON, and that this action be dismissed with prejudice as to defendant ENDOVASCULAR TECHNOLOGIES, INC.

Dated: Jun 13 2008 /s/ Jack Komar
HON. JACK KOMAR
JUDGE OF THE
SUPERIOR COURT

EXHIBIT A

ORDER AFTER HEARING REGARDING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT, OR ALTERNATIVELY, FOR SUMMARY ADJUDICATION

SUPERIOR COURT OF CALIFORNIA
COUNTY OF SANTA CLARA

LILLIAN JOHNSON, Plaintiff, vs. ENDOVASCULAR TECHNOLOGIES, INC., Defendant.	Case No.: 1-05-CV-037784 **ORDER AFTER HEARING REGARDING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT, OR ALTERNATIVELY, FOR SUMMARY ADJUDICATION** Hearing Date: May 16, 2008 Time: 9:00 a.m. Department: 17C/Complex Civil Judge: Hon. Jack Komar

This is a products liability and personal injury action. Plaintiff Lillian Johnson ("Johnson") alleges she was injured after a defective medical device, the Ancure Endograft System ("ANCURE System"), was implanted in her. The device is used for abdominal aortic aneurysm repair. Defendant is alleged to have designed, manufactured, advertised, and sold the product.

Johnson's First Amended Complaint, filed on June 14, 2005, sets forth the following causes of action: [1] Strict Product Liability (Failure to Warn); [2] Strict Product Liability (Pursuant to Restatement Second of Torts §402A (1965)); [3] Negligence; [4] Breach of Express Warranty; [5] Breach of Implied

Warranty; [6] Fraudulent Concealment; [7] Punitive Damages; [8] Violations of the Consumer Legal Remedies Act, Civil Code § 1750, *et seq.;* and [9] Fraud and Misrepresentation.

Defendant now moves for summary judgment or, in the alternative, summary adjudication based on federal preemption.

DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Defendant contends that the United States Food and Drug Administration's ("FDA") premarketing approval ("PMA") process imposes "requirements" that preempt additional or different state requirements. The PMA process is used for Class III devices, which receive the most federal oversight. The ANCURE System is a Class III device.

Under the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act ("MDA") [21 USCS §§ 301 *et seq.*],

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> which relates to the safety or effectiveness of the device or to any other matter included in

> a requirement applicable to the device under this Act
>
> (21 USCS §360k.)

The PMA process imposes "requirements" under the MDA and state claims underlying negligence, strict-liability, and implied-warranty causes of action also constitute "requirements" and are therefore preempted under the MDA. (*Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008).)

Plaintiff Johnson alleges in her amended complaint under state law that defendants failed to perform adequate testing and failed to provide adequate warning to users of the ANCURE System. However, the uncontradicted evidence is that the FDA approved the testing, and specified the warning requirements used by defendants. To the extent Johnson contends defendants needed to perform further testing and provide additional warnings, those would be additional requirements that are preempted by the MDA because of the FDA's earlier approval rough the PMA process.

Johnson argues that where the FDA has acted upon the fraudulent conduct of the defendant, a plaintiff's state law claims will not be preempted, citing the concurring opinion of Justice Stevens in *Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341. *Buckman* involved injuries resulting from the use of orthopedic bone screws. (*Buckman Co. v. Plaintiffs' Legal Committee, supra,* 531 U.S. at p. 343.) The majority opinion in Buckman held that:

> [T]he plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the Agency to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law.
>
> (*Id.* at p. 348.)

Justice Stevens's concurrence in *Buckman* opined that " . . . [t]his would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the § 510(k) process and had then taken the necessary steps to remove the harm-causing product from the market. Under those circumstances, respondent's state-law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation it would be grounded in the agency's explicit actions. In such a case, a plaintiff would be able establish causation without second-guessing the FDA's decision-making or overburdening its personnel, thereby alleviating the Government's central concerns regarding fraud-on-the-agency claims." (*Buckman Co. v. Plaintiffs' Legal Committee, supra,* 531 U.S. at p. 354.)

While Johnson argues that she should be permitted to proceed on claims that are premised on fraud on the FDA, citing the Stevens concurrence in *Buckman* (*supra*), Johnson neither pleads such in her amended complaint relating to the approval nor presents any evidence that would establish there was any fraud on the FDA that affected the pre-approval process that preceded the surgery and implantation of the device; nor does she plead or present evidence that the FDA withdrew its approval and ordered the device off the market. To the contrary, Defendants present evidence that the FDA never removed the ANCURE System from the market, but rather on August 17, 2001, it re-approved the system. Johnson provides no evidence showing otherwise. Thus, even if Justice Stevens's concurring opinion is good law, there is no basis for its application here.

This is essentially a defective device and failure to warn case. Therefore, Johnson's first Amended Complaint is preempted by the MDA because the ANCURE System was approved and then reapproved by the FDA after going through the PMA process.

ORDER

Defendant's motion for summary judgment is GRANTED.

SO ORDERED.

Dated: May 19, 2008 /s/ Jack Komar
Judge of the Supreme Court
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SUPERIOR COURT OF CALIFORNIA

COUNTY OF SANTA CLARA –
UNLIMITED CIVIL JURISDICTION

MICHAEL J. MCGUAN, Plaintiff, v. ENDOVASCULAR TECHNOLOGIES, INC., GUIDANT CORPORATION, ADVANCED CARDIOVASCULAR SYSTEMS, INC.,	Case No.: 1-04-CV-025603 ~~{PROPOSED}~~ **ORDER DENYING PLAINTIFF'S MOTION FOR LEAVE TO AMEND COMPLAINT**

and ORIGIN MED-SYSTEMS, INC., Defendants.	)	Date Action Filed: March 21, 2005 Trial Date: None Set

On June 13, 2008, plaintiff MICHAEL J. McGUAN's Motion for Leave to Amend Complaint came on for hearing before this Court, Having duly considered the matter, the Court hereby DENIES plaintiff's Motion in favor of defendants Endovascular Technologies, Inc., Guidant Corporation, Advance Cardiovascular Systems, Inc., and Origin Medsystems, Inc.

IT IS SO ORDERED.

Dated: June JUN 23 2008, 2008

/s/ Jack Komar
HON. JACK KOMAR
JUDGE OF THE
SUPERIOR COURT

APPROVED AS TO FORM:

Dated: June 19, 2008

AUDET & PARTNERS, LLP

By: /s/ Joseph E. Russell
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SUPERIOR COURT OF CALIFORNIA

COUNTY OF SANTA CLARA –
UNLIMITED CIVIL JURISDICTION

LILLIAN JOHNSON, Plaintiff, v. ENDOVASCULAR TECHNOLOGIES, INC., Defendant.	CASE NO.: 1:05-CV-037784 ~~{PROPOSED}~~ **ORDER DENYING PLAINTIFF'S MOTION FOR LEAVE TO AMEND COMPLAINT** Action Filed: March 21, 2005 Trial Date: None Set

On June 13, 2008, plaintiff LILLIAN JOHNSON's Motion for Leave to Amend Complaint came on for hearing before this Court. Having duly considered the matter, the Court hereby DENIES plaintiff's Motion in favor of defendant Endovascular Technologies, Inc.

IT IS SO ORDERED.

Dated: June JUN 23 2008, 2008

/s/ Jack Komar
HON. JACK KOMAR
JUDGE OF THE
SUPERIOR COURT

APPROVED AS TO FORM:

Dated: June 19, 2008

AUDET & PARTNERS, LLP

By: /s/ Joseph E. Russell
JOSEPH E. RUSSELL
Attorneys for Plaintiff
LILLIAN JOHNSON

Court of Appeal, Sixth Appellate District – No. H033287

S181865

IN THE SUPREME COURT OF CALIFORNIA

En Banc

(Filed Jun. 9, 2010)

MICHAEL C. McGUAN, Plaintiff and Appellant,

v.

ENDOVASCULAR TECHNOLOGIES, INC. et al.,
Defendants and Respondents.

The petition for review is denied.

GEORGE
Chief Justice

Court of Appeal, Sixth Appellate District – No. H033290

S181861

IN THE SUPREME COURT OF CALIFORNIA

En Banc

(Filed Jun. 9, 2010)

LILLIAN JOHNSON, Plaintiff and Appellant,

v.

ENDOVASCULAR TECHNOLOGIES, INC.,
Defendant and Respondent.

The petition for review is denied.

GEORGE
Chief Justice

21 USC § 360k. State and local requirements respecting devices

(a) General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§ 301 et seq.] to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§ 301 et seq.].

(b) Exempt requirements. Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

(1) the requirement is more stringent than a requirement under this Act [21 USCS §§ 301 et seq.] which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act [21 USCS §§ 301 et seq.].

HISTORY:

(June 25, 1938, ch 675, Ch. V, Subch A, § 521, as added May 28, 1976, P.L. 94-295, § 2, 90 Stat. 574; Jan. 4, 1983, P.L. 97-414, § 2(b), 96 Stat. 2051.)

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21 USC § 337. Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this Act [21 USCS §§ 301 et seq.] shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of sections 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(k), 403(q), or 403(r) [21 USCS § 341, 343(b), (c), (d), (e), (f), (g), (h), (i), (k), (q), or (r)] if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1) –

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

HISTORY:

(June 25, 1938, ch €75, Ch. III, § 310 [307], 52 Stat. 1046; Sept. 3, 1954, ch 1263, § 37, 68 Stat. 1239; Nov. 8, 1990, P.L. 101-535, § 4, 104 Stat. 2362; May 13, 1992, P.L. 102-282, § 2, 106 Stat. 150.)

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SUPERIOR COURT OF CALIFORNIA

COUNTY OF SANTA CLARA

MICHAEL J. McGUAN, Plaintiff, vs. ENDOVASCULAR TECHNOLOGIES, INC., GUIDANT CORPORATION, ADVANCED CARDIOVASCULAR SYSTEMS, INC., and ORIGIN MEDSYSTEMS, INC., Defendants.	CASE NO.: 104-CV025603 **PLAINTIFF MCGUAN'S NOTICE OF MOTION AND MOTION FOR LEAVE TO AMEND COMPLAINT** Related Documents: Memorandum of Points & Authorities Declaration of Joseph E. Russell in Support of Motion for Leave to Amend Complaint [Amended w/Wirkus pg|ln] Declaration of Joseph E. Russell in Opposition to Motions for Summary Judgment (Federal Preemption) and in Support of Motions

) to Amend Complaints
) [electronically filed 5-5-08]
) [Proposed] Order
)
) Date: Date: June 6, 2008
) Time: 9:00 a.m.
) Dept: 17
) Judge:
) The Honorable Jack Komar
)
) Action Filed: August 23, 2004
) Trial Date: No Date Set

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on June 6, 2008, at 9:00 a.m. in Department 17 of this Court, located at 161 N. First Street, San Jose, California, Plaintiff Michael J. McGuan will move the Court, pursuant to Code of Civil Procedure 473, for leave to amend his Complaint in this action. Plaintiff seeks leave to add a cause of action for fraud on the Food and Drug Administration ("FDA"), plaintiff's physician and plaintiff.

Plaintiff seeks leave to amend his Complaint as a result of discovery recently obtained in this litigation concerning the facts and circumstances known to defendants prior to plaintiff's implant on July 17, 2001, Guidant's communications with the FDA about such facts and circumstances, and the 2003 Plea Agreement between Defendant Endovascular Technologies, Inc. ("EVT") and the federal government regarding the Ancure Device.

In accordance with California Rule of Court 3.1324, the proposed **First Amended Complaint is attached hereto**. Factual and legal allegations regarding fraud on the FDA have been added in plaintiff's new Cause of Action No. [7], and previous Causes of Action numbered [7 and 8] are now numbered [8 and 9], respectively.

Plaintiff's Motion is based upon this Notice and Motion and the Memorandum of Points and Authorities in Support of Plaintiff's Motion for Leave to Amend Complaint, the Declaration of Joseph E. Russell In Support Of Motion for Leave to Amend Complaint, the [Amended w/ Wirkus Pg[Ln] Declaration of Joseph E. Russell in Opposition to Motions for Summary Judgment (Preemption) and in Support of Motions to Amend, [electronically filed in *McGuan v. EVT*, 5-5-08], the Court's record in this action, the discovery in this action, and any further evidence or argument the Court may properly receive at or before the hearing.

Dated: May 12, 2008 AUDET & PARTNERS, LLP

/s/ Joseph E. Russell
Joseph E. Russell

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SUPERIOR COURT OF CALIFORNIA

COUNTY OF SANTA CLARA

MICHAEL J. McGUAN, Plaintiff, vs. ENDOVASCULAR TECHNOLOGIES, INC., GUIDANT CORPORATION, ADVANCED CARDIO-VASCULAR SYSTEMS, INC., and ORIGIN MEDSYSTEMS, INC., Defendants.	CASE NO.: 104-CV025603 **FIRST AMENDED COMPLAINT JURY TRIAL DEMAND**

* * *

SEVENTH CAUSE OF ACTION

[Fraud on the FDA (and on plaintiff's physician and on plaintiff)

62. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

63. Pursuant to the terms of the FDA's premarket approval of Ancure and to federal regulations, Guidant was legally required, among other things, to provide accurate and complete information to the FDA about the its commercial experience implanting the Ancure Device.

64. Contrary to these responsibilities, Guidant failed to report to the FDA the true facts known to Guidant concerning the safety and effectiveness of the commercial use of the Ancure delivery system, which true facts were and are that Guidant starting in at least early 2000 was in serious violation of FDA regulations concerning most facets of quality control, that Guidant had inadequate data to show the Ancure delivery system was safely used during commercial implants, and that Guidant' failures to obtain FDA approval for changes to the delivery system and procedures, and failures to submit thousands of required Medical Device Reports to the FDA, were intentional by Guidant senior management.

65. Guidant, by affirmative misrepresentations and/or intentional falsehoods and deceptions, provided false information to the FDA which purported to

show that the Ancure Device was safe and effective in repairing aneurysms during commercial use, when in fact Defendant knew that it did not have data to show its effective and safe use.

66. Guidant intentionally, willfully and/or maliciously concealed or failed to disclose to the FDA the true facts with respect to the safety and effectiveness of the commercial use of the Ancure delivery system, despite knowing or having reason to have known the true facts.

67. Guidant made the misrepresentations with the intention that the FDA would rely on them in 2001, in deciding to allow the device to continue being implanted in patients, in deciding whether to allow the device to go through a re-approval process after Guidant recalled the device, and in deciding to allow the device to be re-approved; and they made the misrepresentations with the intent that physicians and patients, including the Plaintiff, would rely on them in selecting the Ancure device for implantation. The FDA and physicians and patients in turn relied on the misrepresentations.

68. At all times mentioned herein, and as a result of Guidant's fraudulent conduct, neither the FDA nor the Plaintiff nor his physician were aware of the true facts with respect to the effectiveness and safety of the commercial use of the Ancure delivery system. The FDA later became partially aware of the facts in its investigation leading to the conviction of EVT/Guidant in 2003. Had the FDA and Plaintiff's

physician been aware of the true facts, the device would have been disapproved by the FDA and the Plaintiff's physician would not have used the device to repair plaintiff's aneurysm. Had Plaintiff been aware of these facts, he would not have acquiesced to the use by his physician of the Ancure Device to aid in the repair of the aneurysm.

69. Guidant knew when they provided false, misleading and/or inadequate information to, and/or concealed information about the commercial use of the Ancure system, the FDA that the FDA, physicians and patients would rely upon this information in making decisions regarding the use of the Ancure Device. Guidant further knew that patients such as Plaintiff would potentially be injured or die as a result of an unsafe and ineffective product due to their fraud on the FDA.

70. As a result of Guidant's concealment and/or suppression of the facts as set forth above, and/or as a result of Guidant' affirmative misrepresentations and/or intentional falsehoods and deceptions as set forth above, Plaintiff sustained injuries and damages as herein set forth.

71. In acting as alleged herein, Guidant acted with oppression, fraud and malice, and Plaintiff is therefore entitled to punitive damages in an amount (1) reasonably related to Plaintiff's actual damages and to Guidant's wealth, and (2) sufficiently large to serve as an example to others and to deter these

Guidant and other entities and individuals from engaging in similar conduct in the future.

* * *

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Attorneys for Plaintiff

SUPERIOR COURT OF CALIFORNIA

COUNTY OF SANTA CLARA

LILLIAN JOHNSON, Plaintiff, vs. ENDOVASCULAR TECHNOLOGIES, INC., Defendant.	CASE NO: 105-CV037784 **PLAINTIFF JOHNSON'S NOTICE OF MOTION AND MOTION FOR LEAVE TO AMEND COMPLAINT** Related Documents: Memorandum of Points & Authorities Declaration of Joseph R. Russell in Support of Motion for Leave to Amend Complaint [Amended w/ Wirkus pg\ln] Declaration of Joseph E. Russell in Opposition to Motions for Summary Judgment (Federal Preemption) and in Support of Motions to Amend

) Complaints [electronically
) filed in McGuan v. Guidant,
) 5-5-08]
) Declaration of Jessica Hawk
) in Support of Evidentiary
) Objections and Motion to
) Amend Complaint
) [electronically filed in
) McGuan v. Guidant, 5-5-08]
) [Proposed] Order
)
) Date: Date: June 6, 2008
) Time: 9:00 a.m.
) Dept: 17
) Judge:
) The Honorable Jack Komar
)
) Action Filed: March 21, 2005
) Trial Date: None Set

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on June 6, 2008, at 9:00 a.m. in Department 17 of this Court, located at 161 N. First Street, San Jose, California, Plaintiff Lillian Johnson will move the Court, pursuant to Code of Civil Procedure 473, for leave to amend her Complaint in this action. Plaintiff seeks to re-add Guidant Corporation ("Guidant") as a named defendant, and to add a cause of action for fraud on the Food and Drug Administration ("FDA").

Plaintiff seeks leave to amend her Complaint as a result of discovery recently obtained in this litigation concerning the facts and circumstances leading

up to the recall and stop shipment of the Ancure Device in March 2001, Guidant's communications with the FDA about such facts and circumstances, and the 2003 plea agreement between Defendant Endovascular Technologies, Inc. ("EVT") and the federal government regarding the Ancure Device.

In accordance with California Rule of Court 3.1324, the proposed **Second Amended Complaint is attached hereto.** Factual and legal allegations regarding fraud have been added in plaintiff's new Tenth Cause of Action. In addition, Guidant has been added to the case caption and factual and legal allegations regarding Guidant have been re-added in paragraph 4 and new paragraph 5, which are both now identical to those same numbered paragraphs in plaintiff's original complaint. Guidant has also been re-added throughout the Complaint as one of the "Defendants."

Plaintiff's Motion is based upon this Notice and Motion and the Memorandum of Points and Authorities in Support of Plaintiff's Motion for Leave to Amend Complaint, the Declaration of Joseph E. Russell In Support Of Motion for Leave to Amend Complaint, the "[Amended w/ Wirkus Pg|Ln] Declaration of Joseph E. Russell in Opposition to Motions for Summary Judgment (Preemption) and in Support of Motions to Amend," electronically filed on May 5, 2008, the Declaration of Jessica Hawk in Support of Evidentiary Objections and Motion to Amend Complaint, also electronically filed on May 5, 2008, the Court's record in this action, the discovery in this

action, and any further evidence or argument the Court may properly receive at or before the hearing.

AUDET & PARTNERS, LLP

Dated: May 12, 2008 /s/ Joseph E. Russell
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SUPERIOR COURT OF CALIFORNIA
COUNTY OF SANTA CLARA

LILLIAN JOHNSON, Plaintiff, vs. ENDOVASCULAR TECHNOLOGIES, INC., Defendant.	CASE NO: 105-CV037784 **SECOND AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

* * *

NINTH CAUSE OF ACTION

[Fraud and Misrepresentation]

78. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

79. At all times mentioned herein, Defendant had the duty and obligation to disclose to Plaintiff and to Plaintiff's physicians, the true facts concerning the Ancure Device product; that is, that said product was dangerous, defective, and likely to cause serious consequences to users, including injuries as herein occurred. Specifically,

a. Defendant knowingly disseminated material misrepresentations to Plaintiff, her physicians, and the general public about the Ancure device's safety and propensity to fail.

b. Defendant misrepresented the safety and efficacy of the Ancure device in labeling, advertising, and promotional materials;

c. Defendant made understatements in reports of the Ancure device and failure rate when Defendant knew the predictable and reasonable probable rate was significantly higher;

d. Defendant disseminated false and misleading information in connection with the recall of the Ancure device in March 2001, which information was calculated to deceive the medical community, governmental agencies, plaintiffs and the general public about the true facts concerning the recall;

e. Knowing that its second pre-marketing testing of the Ancure device was inadequate, Defendant promoted and sold the Ancure device but failed to provide adequate warnings to plaintiffs and the general public which fairly reflected the risks known to Defendant;

f. Defendant made false and misleading statements that the modifications to the Ancure device "instructions for use" eliminated the malfunctions and failures of the Ancure device, when in fact, Defendant knew or reasonably should have known that Ancure devices implanted using the modified instructions caused the same malfunctions and failures and presented significant risks to patients;

g. Defendant made these misrepresentations with the intention that patients, including

the Plaintiff, physicians and the consuming public would rely on them in selecting the Ancure device.

80. Defendant made the misrepresentations as set forth above to Plaintiff, Plaintiff's physicians and the general public prior to the date the Ancure Device was inserted into Plaintiff about the safety and effectiveness of the Ancure device.

81. Defendant made material misrepresentations that were calculated to deceive the medical community, governmental agencies, and Plaintiff about the true facts concerning the safety of the Ancure device.

82. Defendant's misrepresentations about the safety and effectiveness of the Ancure device were material facts essential to the analysis undertaken by the Plaintiff and such that the Plaintiff would not have acted as she did without such misrepresentations.

83. At all times herein mentioned, Defendant intentionally, willfully, maliciously, and affirmatively misrepresented the material facts set forth above to Plaintiff and Plaintiff's physicians, with the intent to defraud as herein alleged and with a knowledge of their falsity.

84. At all times herein mentioned, Defendant intentionally, willfully, maliciously, and affirmatively misrepresented the material facts set forth above to

Plaintiff and Plaintiff's physicians with the intent to induce the Plaintiff to alter her position.

85. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the facts set forth above, and, had she been aware of said facts, she would not have acted as she did, that is, would not have utilized the product to aid in the repair of the aneurysm.

86. As a result of Defendant's affirmative misrepresentation of the facts set forth above, Plaintiff justifiably relied on the Defendant's affirmative misrepresentations and sustained injuries and damages as hereinafter set forth.

87. In doing the actions herein alleged, Defendant acted with oppression, fraud, and malice and Plaintiff is therefore entitled to punitive damages in an amount reasonably related to Plaintiff's actual damages and to Defendant's wealth and sufficiently large to be an example to others and to deter these Defendant and others from engaging in similar conduct in the future.

88. That at all times herein mentioned, Defendant intentionally, willfully, and maliciously misrepresented the facts set forth above to Plaintiff's physicians and therefore to Plaintiff with the intent to defraud Plaintiff as herein alleged.

TENTH CAUSE OF ACTION

[Fraud on the FDA]

89. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

90. Pursuant to the terms of the FDA's pre-market approval of Ancure and to federal regulations, Guidant was legally required, among other things, to provide accurate and complete information to the FDA about the its commercial experience implanting the Ancure Device.

91. Contrary to these responsibilities, Guidant failed to report to the FDA the true facts known to Guidant concerning the safety and effectiveness of the commercial use of the Ancure delivery system, which true facts were and are that Guidant starting in at least early 2000 was in serious violation of FDA regulations concerning most facets of quality control, that Guidant had inadequate data to show the Ancure delivery system was safely used during commercial implants, and that Guidant' failures to obtain FDA approval for changes to the delivery system and procedures, and failures to submit thousands of required Medical Device Reports to the FDA, were intentional by Guidant senior management.

92. Guidant, by affirmative misrepresentations and/or intentional falsehoods and deceptions, provided false information to the FDA which purported to show that the Ancure Device was safe and

effective in repairing aneurysms during commercial use, when in fact Defendant knew that it did not have data to show its effective and safe use.

93. Guidant intentionally, willfully and/or maliciously concealed or failed to disclose to the FDA the true facts with respect to the safety and effectiveness of the commercial use of the Ancure delivery system, despite knowing or having reason to have known the true facts.

94. Guidant made the misrepresentations with the intention that the FDA would rely on them in 2001, in deciding to allow the device to continue being implanted in patients, in deciding whether to allow the device to go through a re-approval process after Guidant recalled the device, and in deciding to allow the device to be re-approved; and they made the misrepresentations with the intent that physicians and patients, including the Plaintiff, would rely on them in selecting the Ancure device for implantation. The FDA and physicians and patients in turn relied on the misrepresentations.

95. At all times mentioned herein, and as a result of Guidant's fraudulent conduct, neither the FDA nor the Plaintiff nor his physician were aware of the true facts with respect to the effectiveness and safety of the commercial use of the Ancure delivery system. The FDA later became partially aware of the facts in its investigation leading to the conviction of EVT/Guidant in 2003. Had the FDA and Plaintiff's

physician been aware of the true facts, the device would have been disapproved by the FDA and the Plaintiff's physician would not have used the device to repair plaintiff's aneurysm. Had Plaintiff been aware of these facts, he would not have acquiesced to the use by his physician of the Ancure Device to aid in the repair of the aneurysm.

96. Guidant knew when they provided false, misleading and/or inadequate information to, and/or concealed information about the commercial use of the Ancure system, the FDA that the FDA, physicians and patients would rely upon this information in making decisions regarding the use of the Ancure Device. Guidant further knew that patients such as Plaintiff would potentially be injured or die as a result of an unsafe and ineffective product due to their fraud on the FDA.

97. As a result of Guidant's concealment and/or suppression of the facts as set forth above, and/or as a result of Guidant' affirmative misrepresentations and/or intentional falsehoods and deceptions as set forth above, Plaintiff sustained injuries and damages as herein set forth.

98. In acting as alleged herein, Guidant acted with oppression, fraud and malice, and Plaintiff is therefore entitled to punitive damages in an amount (1) reasonably related to Plaintiff's actual damages and to Guidant's wealth, and (2) sufficiently large to serve as an example to others and to deter these

Guidant and other entities and individuals from engaging in similar conduct in the future.

* * *